Healthcare of the Future
T. Bürkle et al. (Eds.)

doi:10.3233/978-1-61499-961-4-91

The EU Falsified Medicines Directive A Concept for Drug Decommissioning in Hospitals

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Abstract. The EU falsified Medicines Directive 2011/62/EU will be applied in Switzerland as well. It mandates unique identifiers on medication packages and a process to ensure that these identifiers are decommissioned when the medication package is handed to the patient. While this is not a major problem for Swiss community pharmacies, it is yet unclear how decommissioning shall be managed within hospitals. This paper analyses the drug supply chain in 5 Swiss hospitals and drafts a system architecture to support a decommissioning process upon arrival of new drug deliveries at the hospital pharmacy.

Keywords. Medication process, IT support, hospital pharmacy, commissioning

1. Introduction

The European Union falsified medication directive 2011/62/EU from 2011 has been implemented to protect the EU from an increasing number of falsified medicinal products which reach the patients via the legal supply chain [1]. It has been supplemented with the commission delegated regulation (EU) 2016/161 [2] and amends the old directive 2001/83/EC from 2001 [3] to establish essentially the following mechanisms:

- Medicinal products subject to prescription shall bear specific safety features including a unique identifier (data matrix barcode) for the individual package
- Importers, manufacturers and distributors shall be registered with competent authorities.
- Member states shall provide national repository systems to ensure that falsified medicinal products can be detected and recalls be issued.
- These repository systems shall be interoperable with those in the other member states [1,2] using an exchange hub.
- Persons authorized to supply medicinal products to the public shall be obliged to decommission the unique identifier when supplying the product to the public.
- The marketing authorization holders shall ensure the decommissioning of the unique identifiers of recalled or withdrawn medicinal products.

The regulation shall come into force 9 February 2019 [2]. This implies that Switzerland, as an "associated" state, will establish a Swiss Medicines Verification System – SMVS, which will be connected to the European hub [4]. Swiss pharmacies or physicians, when

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handing a medication package to the patient, will have to decommission the respective unique identifier.

Our activity centered around the question "How will Swiss hospitals deal with the task of decommissioning individual medication packages for their patients?"

2. Methods

2.1. Methods for analysis

The first part focused on an analysis of the current medication supply chain of five Swiss hospitals participating in the "Hospital of the Future Live" project [5]. We conducted semi-structured interviews with the hospital pharmacists, focusing on the order and supply chain from the retailer to the pharmacy and the drug commissioning and distribution process within the hospital to wards, clinics and departments. For feedback, the interviews were supplemented with follow up telephone calls and email communication. Workflows were translated into ARIS event-driven process chains (ePK) which were fed back to the respective hospital for verification. In addition, a comparative matrix of similarities and differences in the medication supply chain among the five hospitals was drafted.

2.2. Methods for defining the technical infrastructure and for mockup development

The second part comprised the recommendation of a future technical infrastructure for Swiss hospitals to comply with directive 2011/62/EU. Based upon the results of the analysis, six different options for the decommissioning of the drug package unique identifier could be identified. The five options within the hospital were discussed again with the pharmacists of the involved hospitals. It turned out that just one of these five options was acceptable for all 5 hospitals. Use case diagrams and a system architecture with all involved IT applications were drafted for this option. IT interfaces required for existing applications were identified and a user mockup was designed using Balsamiq and implemented using xampp with html, php and css.

3. Results

3.1. Analysis results

The participating hospitals had between 237 beds to 1'445 beds. A total of four workflow diagrams with some 20 activities plus associated roles, documents and IT systems were drafted, two for the external supply chain between wholesaler and hospital pharmaceutical depot, and two for the internal commissioning workflow between pharmacy and clinical departments. Two groups of hospitals could be identified. In a group of two hospitals (B and D) the ward dispensary is managed by a certified nurse who places drug orders for the ward at the hospital pharmacy and accepts the delivery of these drugs. The drugs are delivered by hospital transport services. The other three hospitals (A, C, E) have pharmaceutical assistants who manage some or all nursing wards. These pharmaceutical assistants are responsible for re-stocking of the ward dispensaries. They either deliver the drugs themselves to the ward or via the hospital transport services. In the latter case nurses are not involved in the drug order process.

All five hospitals agreed on the decommission of drug packages upon arrival in the hospital pharmacy; three hospitals would be able to establish checkout when drugs leave the pharmacy and two hospitals would be able to establish checkout when drugs arrive at the ward (see table 1).

Table 1. Options for the decommissioning of dispensed drug packages, five Swiss hospitals

Checkout	A	B	C	D	E
on arrival in pharmacy	ok	ok	ok	ok	ok
when delivering to ward	ok	ok	ok	rather no	rather no
when arriving on the ward	ok	no	ok	no	no
when preparing drugs on ward	no	no	no	no	no
when dispensing to the patient	hardly	hardly	hardly	hardly	hardly

3.2. Recommended technical infrastructure and mockup

Interestingly, all 5 hospitals used the SAP materials management system MMS for drugs. Thus, a generic system architecture (fig 1) could be drafted for option one from table 1 (checkout of the unique package identifiers upon arrival of drugs in the pharmacy).

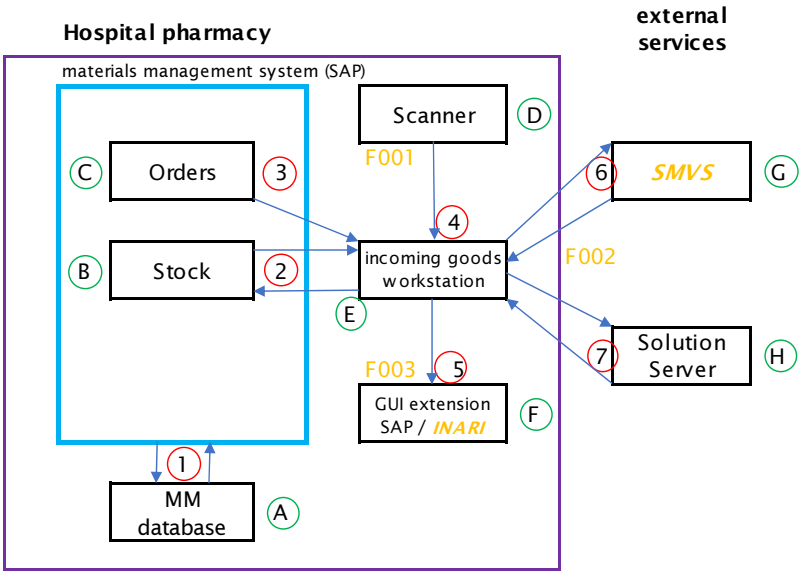

Figure 1. Proposed system architecture. Blue existing materials management system with database (A), in stock information (B) and order information (C), connected to one or more workstations with scanner (E, D) at incoming goods receiving area. Required new functions and components in yellow. F001: Scanner must be able to read new unique identifiers. F002: Scan workstation respectively material management system must communicate with SMVS for decommissioning. F003 User interface extension must be provided to display results of SMVS checkout process.

The SAP MMS could be supplemented with additional functionality either from SAP itself or a third-party supplier to enable the decommissioning of drug packages from SMVS. The scanning workstations at incoming goods need added functionality to scan the GS1 data-matrix of the drug package unique identifier (F001). This can be a new

functionality of the existing MMS or a separate application. F002 interfaces with the SVMS to decommission the unique identifier for each scanned package. A GUI extension must be either added to the MMS or implemented as a plugin to display results of the decommissioning process (F003). Drug packages which couldn't be successfully decommissioned may not be added to stock. These drug packages cannot be accepted by the hospital pharmacy.

4. Discussion

A Medline search for "hospital pharmacy commissioning" delivers a mere 28 hits and none relates to IT support for the process. There is one Polish paper [7] that discusses the effects of directive 2011/62/EU upon the Polish pharmaceutical industry and Polish pharmacies and emphasizes that "introduction of the FMD in Polish hospital pharmacies will be more difficult than in community pharmacies".

Our partner pharmacists stated that they order up to 95% of all drugs directly from the manufacturer. Thus, they think that essentially the risk of delivery of falsified medications is considerably lower compared to e.g. public pharmacies selling drugs directly to the patient. Therefore, the questioned Swiss hospital pharmacists would prefer an option not described here, namely that the manufacturer himself does the decommissioning when delivering drugs to the hospital pharmacy. All examined Swiss hospitals felt currently unable to support drug decommissioning when dispensing the drug to the patient. This is a strong indicator that those hospitals have not yet achieved closed loop medication for all departments and wards, which would be necessary for this type of checkout. In addition, the patients are given individual doses (e.g. single pills), thus it would be unclear when to check-out the package itself.

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